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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| EXAMINER | |
|---|---|
| DELACROIX MUIRHEI, CYBILLE | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1614 | |

DATE MAILED: 08/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/815,984 | CRABB ET AL. | |
| | Examiner | Art Unit | |
| | Cybille Delacroix-Muirheid | 1614 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *02 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *3,8 and 12-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,8 and 12-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *04/02/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## *Detailed Action*

The following is responsive to the preliminary amendment received April 2, 2004.

Claims 1-2, 4-7, 9-11 are cancelled. New claims 12-34 are added. Claims 3, 8, 12-34 are presented for prosecution on the merits.

## *Information Disclosure Statement(s)*

Applicant's Information Disclosure Statement received April 2, 2004 has been considered. Please refer to Applicant's copy of the 1449 submitted herewith.

## *Claim Rejection(s)—35 USC 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claim 15, 29-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. New claim 15 requires the prevention or treatment of bacteria from the "genus *Ureaplasma*." However, this limitation introduces new matter into the claims. Upon reference to the specification, it is clear that Applicant has support for the treatment or prevention of the species *Ureaplasma urealyticum* (please see page 2, line 8, line 21; page 3, lines 1-20; page 5, lines 33-34). Yet, there is no

support for the treatment or prevention of infections by bacteria that fall within the entire genus of *Ureaplasma*. Thus, this limitation is broader than what was originally disclosed in the specification, i.e *Ureaplasma urealyticum*. One of ordinary skill in the art would not have accepted that the applicant was in possession of the invention as claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 3, 8, 12-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. In claim 3, lines 3-4, the limitation "an antibacterially effective derivative thereof" renders the claims vague and indefinite. When reading the claims in light of the specification, one of ordinary skill in the art would not have been able to determine with a reasonable degree of certainty the particular derivatives encompassed by the claims. Applicant's specification does not define the term "derivative." One of ordinary skill in the art would be unable to conclude from the specification what gemifloxacin derivatives Applicant intends to cover by the claims. Therefore, the metes and bounds of the patent protection desired are unclear.

***Claim Rejection(s)—35 USC 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 3, 8, 12-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hannan et al. (abstract) in view of Kim et al., WO 9842705 (both references already of record).

Hannan et al. disclose that SB-265805, also known as gemifloxacin mesylate (please see specification, page 1, line 11), demonstrates excellent *in*

*vitro* activity against the *Mycoplasma* and *Ureaplasma* species of bacteria. The specific species tested were *Ureaplasma urealyticum, M. pneumoniae, M. fermentans, M. penetrans, M. hominus,* and *M. genitalium*. The MIC range used was 0.001-0.25 microgram/ml, which is "well within the range of expected clinical susceptibility." Hannan et al. conclude by teaching that the results indicate that gemifloxacin mesylate has excellent broad spectrum antimycoplasmal activity, and that the compound should be extremely effective in treating respiratory and urogenital infections caused by *Mycoplasma* spp. Please see the abstract; **MIC Determination; Results**, Table 1; **Conclusions**.

Hannan et al. do not specifically disclose a method of treating or preventing mycoplasma induced infection in a mammal by administering an effective amount of gemifloxacin mesylate to the mammal. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the *in vitro* methods of Hannan et al. by administering gemifloxacin mesylate clinically to mammals in need thereof because, in view of the excellent antimycoplasmal activity demonstrated by the *in vitro* tests performed by Hannan et al., one of ordinary skill in the art would reasonably expect gemifloxacin mesylate to exhibit antimycoplasmal activity *in vivo*. In fact, Hannan et al. even suggest that gemifloxacin mesylate would be useful in treating respiratory and urogenital infections caused by Mycoplasma spp. (please see again page 32, **Conclusions**). Thus, such a modification would have been motivated by the reasonable expectation that mammals, e.g. humans, infected

with or at risk of infection with mycoplasma bacteria would be treated when administered gemifloxacin mesylate.

Additionally, Hannan et al. do not disclose the antibacterial effects of gemifloxacin mesylate sesquihydrate; yet, the Examiner turns to Kim et al., which disclose the use of hydrate derivatives of gemifloxacin such as a sesquihydrate derivative of gemifloxacin (hydration number 1.5) in pharmaceutical compositions for treating bacterial infections. Please see Table 1, page 3; page 7, third full paragraph; claims 1-3 and 13.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use gemifloxacin mesylate sesquihydrate to treat or prevent bacterial infections by mycoplasma because Kim et al. disclose that the hydrated derivatives maintain antibacterial activity and in view of the desirable results obtained by Hannan et al., one of ordinary skill in the art would reasonably expect gemifloxacin mesylate sesquihydrate to effectively treat or prevent bacterial infections by the *Mycoplasma* spp.

Finally, concerning the claimed "effective amount" of gemifloxacin administered, since Hannan et al. establish that the MIC range of 0.001-0.25 micrograms/ml would be within the range of clinical susceptibility, then based on these numbers, it would have been obvious to one of ordinary skill in the art to arrive at a dosage of gemifloxacin effective to exhibit antibacterial effects in a mammal thereby treating or preventing bacterial infections by Mycoplasma bacteria.

***Conclusion***

Claims 3, 8, 12-34 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybille Delacroix-Muirheid** whose telephone number is **571-272-0572**. The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Christopher Low**, can be reached on **571-272-0951**. The fax phone number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDM
August 17, 2004

Cybille Delacroix-Muirheid
Patent Examiner Group 1600